REMARKS

Reconsideration and allowance of all pending claims (claims 16-26) are respectfully requested. Applicants address each of the rejections of the May 6, 2004 Office Action, as follows.

Claims 16-26 Stand Improperly Rejected for Lack of Written Description

Reconsideration and withdrawal of the rejection of claims 16-26 for lack of written description under 35 U.S.C. 112, first paragraph, are respectfully requested. This rejection is improper, because it is based on mischaracterizations of both the scope of the claims and the scope of support taught by the application.

According to the Office Action on page 2:

> "When the claims are analyzed in light of the specification, instant invention encompasses any nucleic acid that encodes any mutated form of p53 which antagonizes wild-type p53-mediated neuronal cell degeneration in vitro; (ii) any site for binding of p53 to DNA; and (iii) any nucleic acid that encodes an antisense RNA which inhibits expression of p53."

However, this is not an accurate depiction of the scope of the pending claims. In particular, all pending composition claims (claims 16-21) require that the nucleic acid construct be contained in a recombinant virus selected from the group consisting of adenovirus, adeno-associated viruses and herpes viruses. All pending method claims (claims 22-26) require administering the nucleic acid construct to neuronal cells. Since the rejection is based on an incorrect and overly broad reading of the scope of the claims, it is improper and should be withdrawn.

This rejection also fails, because it is based on a mischaracterization of the scope of the description contained in this application. According to the rejection, as presented on pages 2 and 3 of the Office Action, the specification fails to provide support for the genus claimed, because the specification provides only one example of each of the groups (i) a nucleic acid that encodes any mutated form of p53 which antagonizes wild-type p53-mediated neuronal cell degeneration in vitro; (ii) any site for binding of p53 to DNA; and (iii) any nucleic acid that encodes an antisense RNA which inhibits expression of p53. In fact, the specification teaches at the bottom of page 4 that forms of p53 known in Michalovitz et al (J. Cell. Bioch. 45 (1991) 22) are negative dominant mutants of p53 capable of entering into competition with the wild-type protein and are useful constructs in the present invention. The specification also teaches, on page 5, that the double-stranded nucleic acids reproducing the site for binding of p53 to DNA taught in El-Deiry et al, Kern et al, and Friedman et al can be used to inhibit the binding site of p53 for DNA.

Since the analysis of patentability under 35 U.S.C. 112, first paragraph, for written description is based on an erroneous interpretation of both the scope of the claims and the scope of the description contained in the specification, this rejection is improper and should be withdrawn.

Claims 16-26 Improperly Rejected for Lack of Enablement

Claims 16-26 stand rejected under 35 U.S.C 112, first paragraph, as encompassing broader constructs than one of skill in the art would be enabled by the disclosure of the specification to make and use. Reconsideration and withdrawal of this rejection are respectfully requested. This rejection is based on the same mischaracterization of the scope of the disclosure of the instant specification described above. Accordingly, this rejection is based on a faulty analysis of the scope of the disclosure and should be withdrawn.

Furthermore, this rejection should fail because it seems to be an improper argument about the utility of the claimed invention, and not actually directed to the enablement issue. The rejection, as presented on pages 4-9 of the Office Action of May 6, 2004, repeatedly states that the specification lacks proof of function for the instantly claimed constructs. For example:

> "Regarding the p53Val135, the specification does not provide any evidence whether this mutant would have antagonized the wild type mediated p53 mediated [sic] neuronal cell degeneration." Page 5 and
>
> "As for the specification, it does not provide any evidence either that p53 caused neuronal cell degeneration and that this mutant of p53 or any other mutant of p53 could antagonize such effects of p53 on neuronal cell." Page 6.

The undersigned attorney respectfully notes that the specification and originally filed claims contain clear statements of the Applicants that the instantly claimed p53 mutants antagonize p53-caused neuronal cell degeneration. In the absence of evidence to the contrary, or a scientifically supported theoretical basis to doubt Applicants statements, it is improper for the Examiner to attack the stated utility of the constructs of the instant claims. It is improper, in any event, for these utility concerns to be miscast as an enablement rejection.

Claims 16, 17, 19-22, 25 and 26 Are Patentable Over the Combination of Michalovitz et al in view of Moberg et al, LaGal La Salle et al and Chopp et al

Reconsideration and withdrawal of the rejection of Claims 16, 17, 19-22, 25 and 26 under 35 U.S.C. 103(a) as being obvious over the combination of Michalovitz et al in view of Moberg et al, LaGal La Salle et al and Chopp et al (Biochemical and Biophysical Research Communications, 1992) are respectfully requested. Applicants note that this combination of prior art is identical to Issue 1 as listed on page 4 of the Appeal Brief filed in this application on February 24, 2004, except that the Chopp et al reference has been added. The first full paragraph on page 10 of the instant

Office Action provides an alleged teaching of Chopp et al, however, there appears to be no statement in the instant rejection of the role of Chopp et al in providing a combination of prior art that would teach or suggest to one of skill in the art the instantly claimed invention. Accordingly, this obviousness rejection appears to be identical to Issue 1 as stated in the Appeal Brief. Applicants, therefore, rely on their arguments for patentability regarding Issue 1, as found on pages 6-11 of the Appeal Brief. These arguments have yet to be addressed in any Official Action.

Claims 16-23, 25 and 26 Are Patentable Over the Combination of Lerero et al in view of Michalovitz et al, Funk et al and Chopp et al

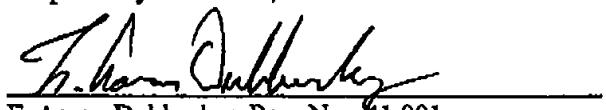
Reconsideration and withdrawal of the rejection of Claims 16-23, 25 and 26 under 35 U.S.C. 103(a) as being obvious over the combination of Lerero et al in view of Michalovitz et al, Funk et al and Chopp et al are respectfully requested. Applicants note that this combination of prior art is identical to Issue 2 as listed on page 4 of the Appeal Brief filed in this application on February 24, 2004. Applicants, therefore, rely on their arguments for patentability regarding Issue 2, as found on pages 12-17 of the Appeal Brief. These arguments have yet to be addressed in any Official Action.

Claims 22-26 Are Patentable Over the Combination of Smith in view of Soussi et al and Chopp et al

Reconsideration and withdrawal of the rejection of Claims 22-26 under 35 U.S.C. 103(a) as being obvious over the combination of Smith in view of Soussi et al and Chopp et al are respectfully requested. Applicants note that this combination of prior art is identical to Issue 3 as listed on page 4 of the Appeal Brief filed in this application on February 24, 2004. Applicants, therefore, rely on their arguments for patentability regarding Issue 3, as found on pages 17-19 of the Appeal Brief. These arguments have yet to be addressed in any Official Action.

Applicants respectfully submit that the application is now in condition for allowance and request prompt notice thereof.

Respectfully submitted,



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